

EXHIBIT B

1 A. Uh-huh.

2 Q. Yes?

3 A. Yes.

4 Q. I'm sorry. You've got to answer
5 aloud for her.

6 A. Yes.

7 Q. Were you ever told by Mr. -- is it
8 Ferrara?

9 A. Uh-huh.

10 Q. -- Mr. Ferrara that Bard had a crisis
11 management plan, as early as 2004, to deal with the
12 high rates of AEs, that being, adverse events,
13 perforation, fracture and migration?

14 MS. HELM: Object to the form.

15 THE WITNESS: No.

16 BY MR. MATTHEWS:

17 Q. Were you ever told that Bard
18 conducted an investigation in 2004 into the high
19 number or large number of adverse events of the
20 Recovery done by an independent investigator?

21 MS. HELM: Object to the form.

22 THE WITNESS: No.

23 BY MR. MATTHEWS:

24 Q. Were you ever sent a letter by the
25 company that talked to you or -- I'm sorry, that

As to 33:10-13
& 33:17-20:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403

Rule 611(c)
leading of
witness on
direct.

Rule 402, 403.
This is not
related to the
G2 filter.

As to 33:24-
35:1:
Questions are
all leading,
Rule 611(c).

1 informed you about the results of this
2 investigation, this independent investigation by
3 Bard?

4 MS. HELM: Object to the form.

5 THE WITNESS: No.

6 BY MR. MATTHEWS:

7 Q. Were you ever told, either by letter
8 or by Mr. Ferrara, that there was a 530 percent
9 higher fracture rate than other filters on the
10 market with the Bard Recovery?

11 MS. HELM: Object to the form.

12 THE WITNESS: No.

13 BY MR. MATTHEWS:

14 Q. Were you ever told that there was a
15 1,200 percent higher risk of death from the Recovery
16 fracture and embolization to the heart than other
17 filters on the market?

18 MS. HELM: Object to the form.

19 THE WITNESS: No.

20 BY MR. MATTHEWS:

21 Q. In 2004 and 2005, clearly two years
22 prior to implanting Ms. Booker with the G2, would
23 that have been important information for you to
24 know? Assuming that that was information that was
25 known to Bard, is that something that you would want

Rule 611
assumes facts
not in evidence.

Rule 611(c)
leading of
witness on
direct.

Rule 402, 403
& CMO 31.

Rule 611
assumes facts
not in evidence.

Rule 611(c)
leading of
witness on
direct.

Rule 611(c)
leading of
witness on
direct.

Rule 611
assumes facts
not in evidence.

1 and filter fracture associated with the Recovery
2 filter were seen in the MAUDE database at reporting
3 rates that were 4.6, 4.4, 4.1 and 5.3 higher,
4 respectively, than reporting rates for all other
5 filters.

6 Doctor, this is dated December 17th,
7 2004. Would this have been important information
8 for you to know, that is, a doctor who is implanting
9 Recovery filters, that those filters had a greater
10 risk of fracture that's four and five times higher
11 than the competitor filters?

12 MS. HELM: Object to the form.

13 THE WITNESS: Yes.

14 BY MR. MATTHEWS:

15 Q. Is that the type of information that
16 would influence your prescribing habits, whether you
17 would use that filter, a Bard filter, or another
18 filter?

19 MS. HELM: Object to the form.

20 THE WITNESS: Yes.

21 BY MR. MATTHEWS:

22 Q. Let me show you what's been marked as
23 Exhibit-3, which is the Recovery filter migration,
24 Remedial Action Plan, dated January 4, 2005.

25 - - -

Rule 611(c)
leading of
witness on
direct.

1 (Whereupon, Exhibit-3,
2 BPVE-01-01019773-784, Recovery Filter Migration,
3 Dated 1/4/05, was marked for identification.)

4 - - -

5 BY MR. MATTHEWS:

6 Q. Again, this is a full two and-a-half
7 years prior to implanting Ms. Booker with the G2.

8 And I would turn your attention to
9 the first, second, third, fourth, fifth page. It
10 says, actually, 1 of 7 on the fifth page of that
11 document.

12 A. I'm sorry, could you --

13 Q. At the bottom under Roman III.

14 It says, Identification of the
15 problem: As part of the ongoing evaluation of RNF,
16 Recovery Nitinol filter, Bard requested an
17 independent study of the risks and benefits of the
18 RNF, with an emphasis on its use in bariatric
19 surgery and trauma patients. A consultant was
20 retained for this purpose and reported the
21 following: The MAUDE database maintained by the FDA
22 was reviewed. The reporting rates between the RNF
23 and aggregates of the other commercialized vena cava
24 filters were compared.

25 A, in the MAUDE dataset, the RNF

Rule 403.
Document
refers to
Bariatric and
trauma
patients.
Plaintiff is
neither of
those.

Incomplete
question; also
question was
stricken see
page 39:21-22.

1 demonstrated a consistent statistically significant
2 and potentially clinically important higher rate of
3 reporting of adverse events in several analyzed
4 categories.

5 B, given the pattern of reported
6 events, a higher rate of death reports seem related
7 to filter movement and filter embolization.

8 You referenced the MAUDE database
9 earlier in questions, Doctor. Is that information
10 important to you as a doctor that is implanting the
11 Recovery filter?

12 MS. HELM: Object to the form.

13 MR. LERNER: Which information?

14 MR. MATTHEWS: That is A and B that I
15 just read.

16 MS. HELM: Object to the form.

17 MR. LERNER: But you questioned him,
18 you said you referenced the MAUDE database before.
19 Your question then becomes confusing. I'm asking
20 you to clarify it.

21 MR. MATTHEWS: All right. I'll
22 strike it and ask another question.

23 BY MR. MATTHEWS:

24 Q. In looking at A and B, Doctor, is
25 that the type of information that's important to you

Rule 611(c)
leading of
witness on
direct.

1 to know prior to implanting a Recovery filter?

2 A. Yes.

3 MS. HELM: Object to the form.

4 BY MR. MATTHEWS:

5 Q. Do you know what the term

6 "statistically significant" means?

7 A. I do.

8 Q. And that's an important

9 epidemiological statement, correct?

10 MS. HELM: Object to the form.

11 THE WITNESS: Statistical statement,

12 yes.

13 BY MR. MATTHEWS:

14 Q. Doctor, at the Methodist Hospital in
15 2007, did you have more than one filter at your
16 disposal? That is, you talked about, I think you
17 told me, you had the TRAPEASE, you had the Tulip,
18 and you had the Recovery, and you had the select.

19 Were all of those available back in
20 2007, do you recall?

21 A. No.

22 Q. Do you know which were available?

23 A. The G2.

24 Q. That was the only one available in
25 the hospital?

As to 40:8-9:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403

Rule 611(c)
leading of
witness on
direct.

1 time period are you talking about now?

2 MR. MATTHEWS: Well, that was kind of
3 a general question as to filters in general. So I
4 will leave that open.

5 BY MR. MATTHEWS:

6 Q. Whether you have a medical opinion
7 from your practice, from your reading, from your
8 research, from your treatment of patients, as to
9 which filter failure would be the most dangerous,
10 producing the most serious injury to a patient.

11 MS. HELM: Object to the form.

12 THE WITNESS: I do.

13 BY MR. MATTHEWS:

14 Q. What's your opinion?

15 A. Obviously, all complications are bad,
16 although caval thrombosis can be devastating in
17 terms of lower extremity edema and dysfunction. I
18 think that migration or fracture are more serious
19 events.

20 Q. Were you ever told, at any time prior
21 to today and being shown some documents about the
22 MAUDE database, that Bard evaluated specifically the
23 MAUDE database to compare their filter with others
24 in 2004?

25 MS. HELM: Object to the form.

As to 43:20-24:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 403,
unrelated to
filter at issue.

As to 44:3-8:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 403,
unrelated to
filter at issue.

Rule 611(c)
leading of
witness on
direct.

1 THE WITNESS: No.

2 BY MR. MATTHEWS:

3 Q. Is that the type of information you
4 would expect a manufacturer that sets out to make a
5 decision, or at least look at the MAUDE information
6 to determine filter fracture compared to other
7 filters on the market, is that the type of
8 information you want to know about?

9 MS. HELM: Object to the form.

10 THE WITNESS: Yes. But it's a bit
11 more complicated in the sense that my understanding
12 of the MAUDE database is that it is a voluntary
13 database. It's not legally required for a physician
14 to report a problem with an implant or a product,
15 although you could argue that it is ethically
16 required. As with any database, it has problems
17 with regards to vetting of data, with regards to
18 accuracy of data.

19 So if a concern existed regarding a
20 particular product, yes, I think that should be
21 brought forth and studied, scientifically studied
22 and addressed.

23 BY MR. MATTHEWS:

24 Q. At a bare minimum, the MAUDE database
25 would be a signal, a red flag --

As to 44:24-25:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

1 have been reported without any adverse clinical
2 sequelae.

3 I'd like to ask you about the first
4 sentence: Filter fracture is a known complication
5 of vena cava filters.

6 Doctor, do you read that in the IFU
7 to mean that the rates of filter fracture are
8 similar with all filters?

9 MS. HELM: Object to the form.

10 THE WITNESS: I don't read anything
11 about rate. I read something about complications
12 and about the potential for fracture. So it makes
13 no specific statements with regards to the incidence
14 of this occurrence.

15 BY MR. MATTHEWS:

16 Q. If there is evidence that the company
17 had, in 2006 or prior to that publication being sent
18 to you with the filter, and there was a showing
19 within the company of a 500 percent greater risk
20 with Bard filter compared with other filters, is
21 that the information -- the type of information that
22 you would want to know about?

23 MS. HELM: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. MATTHEWS:

Rule 611(c)
leading of
witness on
direct.

As to 49:16-22:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 611
assumes facts
not in evidence.

Rule 611(c)
leading of
witness on
direct.

1 en masse, to follow that and inform doctors about
2 what they see in the marketplace?

3 A. Yes.

4 Q. Were you ever told by Bard, Mr.
5 Ferrara or anybody at Bard, that they had observed
6 higher rates of complications with Recovery, that
7 they placed it on a temporary commercial hold? Did
8 you ever know that?

9 MS. HELM: Object to the form.

10 THE WITNESS: No.

11 BY MR. MATTHEWS:

12 Q. Were you ever told why Bard withdrew
13 the Recovery from the market?

14 A. No.

15 Q. Were you ever told why Bard withdrew
16 G2 from the market?

17 A. No.

18 Q. Do you know Dr. Murray Ash?

19 A. No.

20 Q. Dr. Ash testified in this case that
21 he conducted a pilot study for the Recovery filter
22 and Bard advised him it would subsequently do a
23 larger safety study.

24 Let me ask you, do you know what a
25 pilot study is versus a clinical trial or --

As to 51:4-8:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 611(c)
leading of
witness on
direct.

1 would I have used a different device if I knew at
2 the time that the Bard filter was not ideal or as
3 good as some of the other implants? The answer
4 would have to be yes.

5 BY MR. MATTHEWS:

6 Q. You would have used --

7 A. I would have used a different filter
8 if there was a different filter that I knew of that
9 was better, in terms of its safety profile.

10 Q. In terms of the documents that you
11 have, I think they are Exhibit-2 and 3, the health
12 hazard report and then the investigation conducted
13 by Bard that showed a fivefold increased risk for
14 fracture and embolization of that fracture, and you
15 told us that would be the type of information you
16 would want to know in your benefit/risk analysis,
17 knowing that --

18 A. Yes.

19 Q. -- and seeing that today, would that
20 have been enough to use another filter?

21 MS. HELM: Object to the form.

22 THE WITNESS: Difficult to say with
23 certainty. It would depend upon what other filters
24 we had at the time and what their problems would
25 have been. But it would have been a very important

As to 63:19-20:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 611(c)
leading of
witness on
direct.

1 piece of information, as far as making decisions

2 regarding this or any other patient, yes.

3 BY MR. MATTHEWS:

4 Q. And it would have influenced your

5 prescribing habit?

6 MS. HELM: Object to the form.

7 THE WITNESS: Yes.

8 BY MR. MATTHEWS:

9 Q. Let me show you a study, I'm going to

10 mark this as D'Ayala Exhibit Number 7. And this is

11 entitled, The Prevalence of Fracture -- I'm sorry,

12 let me hand that to you.

13 A. Sure.

14 Q. The Prevalence of Fracture and

15 Fragment Embolization of Bard Retrievable Vena Cava

16 Filters and Clinical Implications Including Cardiac

17 Perforation and Tamponade.

18 - - -

19 (Whereupon, Exhibit-7, AMA,

20 Prevalence of Fracture and Fragment Embolization of

21 Bard Retrievable Vena Cava Filters and Clinical

22 Implications Including Cardiac Perforation and

23 Tamponade, was marked for identification.)

24 - - -

25 BY MR. MATTHEWS:

As to 64:4-5:
Bard's
Preliminary
Objection No. 1
-- Recovery
Filter/Cephalad
Migration --
Rules 401, 402,
and 403.

Rule 611(c)
leading of
witness on
direct.

1 Q. A retrospective single-center
2 cross-sectional study was conducted by evaluating
3 all patients who received either a Bard Recovery or
4 Bard G2 filter from April 2004 until January 2009.

5 Under the results it says, 13 of 80
6 patients had at least one strut fracture. At least
7 one strut in 7 of the 28 Bard Recovery filters
8 fractured and embolized. In 5 of the 7 cases,
9 patients had at least one fragment embolize to the
10 heart, 71 percent of those that fractured. Three
11 patients experienced life-threatening symptoms of
12 ventricular tachycardia and/or tamponade, including
13 one patient who experienced sudden death at home.
14 Six of 52 Bard G2 filters fractured, 12 percent. In
15 2 of these 6 cases, the patients had asymptomatic
16 end-organ fragment embolization.

17 Did I read that correctly?

18 A. Yes, sir.

19 Q. Okay. The conclusion of this study
20 by Dr. Nicholson and other doctors in different
21 fields of medicine found the Bard Recovery and Bard
22 G2 filters had high prevalence of fracture and
23 embolization with potentially life-threatening
24 sequelae.

25 Doctor, if you had been warned prior

Bard's
objection:
Rule 602 -
asking about
article he had
never seen.
The study post
dates his care
and treatment
of the Plaintiff
(see line 4
above)

Rule 611(c)
leading of
witness on
direct.

1 to June of 2007 of this information, I know this is
2 dated 2010, but I'm going to ask you the question
3 for purposes of a hypothetical, that is, had you
4 known this information of this conclusion, that the
5 G2 had a high prevalence of fracture and
6 embolization with life-threatening sequelae, would
7 that have influenced your prescribing habits and the
8 use of the G2 with Ms. Booker?

9 MS. HELM: Object to the form.

10 THE WITNESS: Yes.

11 BY MR. MATTHEWS:

12 Q. Do you know of any reason back after
13 the pilot study in 2002 why Bard could not have
14 conducted a clinical trial with its G2 and done
15 follow-up with patients from the original pilot
16 study?

17 MR. LERNER: I'm not sure how --

18 MS. HELM: Object to form.

19 MR. LERNER: I'm not sure how he's
20 supposed to be able to answer a question like that.
21 That doesn't seem like a fair question for this
22 doctor.

23 MS. HELM: I object to the form.

24 BY MR. MATTHEWS:

25 Q. I ask you because you have conducted

1 if you extrapolate indwelling time with the G2
2 filter, that making it a 25 percent filter fracture
3 rate for the G2.

4 Do you understand that premise within
5 the paper?

6 A. I think I understand the premise.
7 I'm not so sure that I understand the science behind
8 it.

9 Q. Well, let me ask you this question,
10 then, Doctor: If you knew back in 2007 when you
11 were implanting that filter that there was even a 12
12 percent probability of fracture with that filter,
13 would you have used a G2?

14 MS. HELM: Object to the form.

15 THE WITNESS: Unlikely.

16 BY MR. MATTHEWS:

17 Q. If there was a 25 percent risk of
18 filter fracture, can we safely say you would not
19 have used that filter?

20 A. Most likely. But you have to
21 understand that you have to have a way of treating
22 these difficult patients. So some filter has to be
23 used. And it becomes a matter of deciding which
24 filter is best, so to speak. And sometimes that's
25 not entirely clear.

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Rule 611,
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Affirmative
Designation by
Both Parties